## **REMARKS**

This Amendment is submitted in reply to the non-final Office Action mailed on May 8, 2006. A petition for a one month extension of time is submitted herewith. The Director is authorized to charge \$120.00 for the petition for extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-435 on the account statement.

Claims 1-26 are pending in this application. In the Office Action, Claims 1-2, 13 and 20 are rejected under 35 U.S.C. §112, second paragraph, Claims 11 and 19 are rejected under 35 U.S.C. §101, Claims 11 and 19 are rejected under 35 U.S.C. §112, first paragraph, and Claims 1-26 are rejected under 35 U.S.C. §103. In response Claims 1-2, 10-13 and 14-20 have been amended. This amendment does not add new matter. In view of the amendment and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Claims 12-18 have been amended to properly depend from Claim 11. In addition, Applicants have amended the specification to include the general description of the trademarked resins at the time of filing the present application. No new matter has been added thereby.

In the Office Action, the Patent Office asserts that no IDS was previously filed. Applicants respectfully submit that they filed an IDS on October 18, 2004 and received a stamp postcard (attached as Exhibit A) from the Patent Office showing that they received same. As a courtesy, Applicants resubmit the previously filed IDS as Exhibit B.

In the Office Action, Claims 1-2, 13 and 20 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response, Claim 1 has been amended to address the informalities cited by the Patent Office. Claims 10-11 and 19 have been similarly amended. Applicants have amended Claims 2, 13 and 20 to recite, in part, the general description of the trademark resins. The amendment is supported as discussed in the amendment to the specification above. Based on at least these noted reasons, Applicants believe that the claims fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 11 and 19 are rejected under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the utility requirement and enablement requirement. The Patent Office admits that Claims 11 and 19 meet the specific and substantial utility guidelines for the prevention and or treatment of caries, plaque formation, dental diseases, diseases of the mouth and disease of the gum. See, Office Action, page 4, lines 10-12. However, the Patent Office asserts that Claims 11 and 19 are not a credible or well-established utility for same.

In response, Applicants respectfully submit that an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101. See, e.g., *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977). As the Court of Customs and Patent Appeals stated in *In re Langer*:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented <u>must</u> be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter <u>unless</u> there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d at 1391, 183 USPQ at 297 (emphasis in original). The "Langer" test for utility has been used by both the Federal Circuit and the Court of Customs and Patent Appeals in evaluation of rejections under 35 U.S.C. §112, first paragraph, where the rejection is based on a deficiency under 35 U.S.C. §101. In In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), the Federal Circuit explicitly adopted the Court of Customs and Patent Appeals formulation of the "Langer" standard for 35 U.S.C. §112 first paragraph rejections, as it was expressed in a slightly reworded format in In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971), namely:

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented <u>must</u> be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. (emphasis added).

Thus, Langer and subsequent cases direct the Office to presume that a statement of utility made by an applicant is true. See *In re Langer*, 503 F.2d at 1391, 183 USPQ at 297; *In re* 

Malachowski, 530 F.2d 1402, 1404, 189 USPQ 432, 435 (CCPA 1976); In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). For obvious reasons of efficiency and in deference to an applicant's understanding of his or her invention, when a statement of utility is evaluated, Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the applicant. If the asserted utility is credible (i.e., believable based on the record or the nature of the invention), a rejection based on "lack of utility" is not appropriate. Clearly, Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false based on the technical field of the invention or for other general reasons. See, MPEP 2107.02 III A.

Applicants respectfully submit that one having ordinary skill would not doubt Applicants' assertion of utility regarding treating or preventing a disease or state chosen from the group consisting of caries, plaque formation, dental diseases, diseases of the mouth cavity, and diseases of the gums. Even the Patent Office admits that caseino-glycomacropeptide has been shown to be effective antibacterial agents against microorganisms response for dental plaque and caries. See, Office Action, page 5, lines 12-15. If caseino-glycomacropeptide is effective against microorganisms responsible for dental plaque and caries, the skilled artisan would understand that caseino-glycomacropeptide could be used to prevent or treat caries and plaque formation by addressing and inhibiting the source or cause of same. Because caries and plaque formation lead to dental diseases, diseases of the mouth cavity and diseases of the gums, caseino-glycomacropeptide can be used to prevent or treat same.

In sum, Applicants' Claims 11 and 19 satisfy the utility requirement of 35 U.S.C. §101 because Applicants' Claims 11 and 19 are credible as understood by the skilled artisan as previously discussed. In addition, Applicants' Claims 11 and 19 satisfy the enablement requirement of 35 U.S.C. §112, first paragraph, because the skilled artisan would understand how to make and use the invention of Claims 11 and 19 in view of Applicants' disclosure. For example, Applicants' teach how to make the claimed product and use it in various food and oral hygiene products that can be applied to the oral cavity for preventing and treating caries and plaque forming microorganisms. Based on at least these noted reasons, Applicants believe that Claims 11 and 19 fully comply with 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 11 and 19 under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 1-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,853,704 to Zhang et al. ("Zhang") and U.S. Patent No. 4,530,906 to Higashi et al. ("Higashi") in view of EP 0575121 A1 to Agmon et al. ("Agmon"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claims 1, 10-11 and 19 have been amended for clarification purposes. No new matter has been added. Independent Claims 1, 10-11 and 19 are directed, in part, to a caseino-glycomacropeptide containing composition comprising a hydrophobic resin; and an agent that chemically blocks functional groups in caseino-glycomacropeptide. In contrast, Applicants respectfully submit that the skilled artisan would not be motivated to combine the cited references to arrive at the present claims.

Applicants respectfully submit that there is no suggestion or motivation to combine the cited references to obtain the present claims because they are directed to completely unrelated products and processes. For example, *Zhang* is entirely directed to a dentifrice exhibiting enhanced remineralization that can be delivered from a dual compartment tube or pump device. See, *Zhang*, column 2, lines 11-39.

Agmon is directed to a process for treating food products and by-products such as dairy and soya products to remove off flavors/colors/smells. See, Agmon, page 2, lines 30-49. Preferably, the food products are subjected to a heat treatment or other sterilization step to enable the off flavors/colors/smells to be removed. Id. Agmon fails to disclose or suggest any dentifrice products or that his process could be used with same. Moreover, Zhang fails to disclose that his dentifrices have off flavors/colors/smells that need to be removed.

Higashi is narrowly directed to a method for increasing the milk coagulating activity of microbial rennet from Mucor pusillus microorganisms. See, Higashi, column 1, lines 6-39. Higashi fails to disclose or suggest any dentifrice products or that his process could be used with same. In turn, Zhang dentifrice product is not at all related in any way with Higashi's disclosure. Consequently, there is no direction provided in the cited references suggesting how they should be combined to obtain the present claims.

What the Patent Office has done is to rely on hindsight reconstruction of the claimed invention. Applicants respectfully submit that it is only with a hindsight reconstruction of Applicants' claimed invention that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. Instead, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. In re Fine, 837 F.2d at 1075. (Fed. Cir. 1988).

For at least the reasons discussed above, the combination of *Zhang*, *Higashi* and *Agmon* is improper, and thus, fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1-26 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the aboveidentified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

 $BY \subseteq$ 

Robert M. Barrett Reg. No. 30,142 Customer No. 29157

Dated: September 6, 2006

## **EXHIBIT A**

In re Patent Application of: Braun et al.

Serial No.: 10/506,747

Docket No.: 112701-435

On the date stamped hereon the U.S. Patent and Trademark Office hereby acknowledges receipt of the following:

Transmittal Letter (2 pages) (duplicate); 2.

Executed Declaration and Power of Attorney (2 pages);

Information Disclosure Statement (2 pages); PTO-1449 (1 page); Cited References (1 Document); and

Check in the Amount of \$130.00.

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